



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A01N 37/02, 59/00 // (A01N 37/02, 31:02, 25:30, 25:00) (A01N 59/00, 31:02, 25:30, 25:00)</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/62613 (43) International Publication Date: 26 October 2000 (26.10.00)</p>
<p>(21) International Application Number: PCT/US00/10626 (22) International Filing Date: 19 April 2000 (19.04.00) (30) Priority Data: 60/130,227 20 April 1999 (20.04.99) US 09/373,951 13 August 1999 (13.08.99) US (71) Applicant: EFFCON LABORATORIES, INC. [US/US]; 1800 Sandy Plains Parkway, Suite 108, Marietta, GA 30066 (US). (72) Inventors: KIEL, Jeffrey, S.; 4253 Cherokee Trail, Gainesville, GA 30504 (US). PING, Jeffrey, H.; 316 Park Creek Court, Gainesville, GA 30504 (US). (74) Agents: WARREN, William, L. et al.; Jones & Askew, LLP, 2400 Monarch Tower, 3424 Peachtree Road, N.E., Atlanta, GA 30326 (US).</p>		<p>(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: PEST REMOVING COMPOSITION

(57) Abstract

The present invention provides a composition, and a method of use thereof, that is pesticide-free and yet is capable of cleansing an individual of a pest infestation. The composition of the present invention consists essentially of an acid, an alcohol, an aqueous detergent and water. The composition is used in the removal of pests and their ova from infested individuals. Preferably, the composition of the present invention takes the form of a shampoo and is used to cleanse individuals of lice infestations. In use, the composition is applied to hair and allowed to remain in contact with the hair and scalp for a period of time, called the residence time. After the residence time, the composition is rinsed from the hair. Then, the hair is combed with a suitable nit comb. These treatment steps may be repeated as necessary and appropriate to effectuate the removal of the pest infestation.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Larvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon	KR	Republic of Korea	PL	Poland		
CN	China	KZ	Kazakhstan	PT	Portugal		
CU	Cuba	LC	Saint Lucia	RO	Romania		
CZ	Czech Republic	LI	Liechtenstein	RU	Russian Federation		
DE	Germany	LK	Sri Lanka	SD	Sudan		
DK	Denmark	LR	Liberia	SE	Sweden		
EE	Estonia			SG	Singapore		

5

10

PEST REMOVING COMPOSITION

Related Applications

15

This application claims priority to U.S. Provisional Patent Application, Serial No. 60/130,227, filed on April 20, 1999.

Technical Field

20

The present invention relates to the removal of pests and their ova. Specifically, the present invention relates to the cleansing of an individual of pests and their ova.

Background of the Invention

25

30

35

Pests present a persistent problem to humans and animals alike. A multitude of products and strategies have been developed to attempt to deal with the problems presented by pests. Unfortunately, most of these products have undesirable side effects. Many of the products make use of pesticides which are often toxic to some extent to humans and animals, those the products are designed to protect. Toxicity problems presented by products containing pesticides can pose risks to those using the products and prevent use by some who are especially sensitive to pesticides. These problems can limit the frequency with which the product can be used and thereby limit the effectiveness of the products in cleansing an individual of a pest infestation. These problems can frequently be exacerbated in children who comprise a significant portion of the population afflicted with pest infestations. Other products designed to repel pests often have unpleasant odors making them undesirable options for dealing with pest problems.

One example of the persistent problems caused by pests is the problem caused by the louse. Lice infestations are a persistent problem worldwide. For example, the annual incidents of lice infestations is estimated to be 10 million cases. Furthermore, many of those infected are school age children. Epidemics can occur in school age children, frequently when schools open in the fall. Because a large number of children are brought together in close proximity for prolonged periods, the chances that lice infestations can spread from child to child greatly increase.

Head lice feed on the blood of their hosts by attaching to the scalp and introducing an anticoagulant under the skin during feeding. This feeding frequently induces erythema and pruritus. The resulting scratching by the host may lead to secondary bacterial infections in addition to causing great discomfort.

Because of the wide spread nature of and the problems caused by lice infestations, many products have been developed to try and treat lice infestations. Most of these products are designed to kill and/or repel the lice. Many of these products contained pesticides which are by their nature toxic to some degree. For example, one common active ingredient in prior commercial products is N,N-diethyl-M-toluamide (DEET). However, DEET has recently been associated with causing various undesirable side effects, such as stinging, damage to mucous membranes, and possibly seizures. In 1989, the Centers for Disease Control issued a cautionary statement regarding the use of DEET. Many other prior art compounds proposed for use as lice treatments have also proven unsuitable for topical application to humans or other animals due to their toxic or noxious effect on the infested individual.

Many of the prior products designed to repel lice have had the disadvantage of having an unpleasant smell. Aside from the discomfort associated with the unpleasant smell, this disadvantage also decreases the likelihood that the treatment product will be used with the recommended frequency. Thus, the efficacy of such products is decreased.

Furthermore, many of the prior art products kill or repel only the pests and not their ova. If a treatment does not rid the individual of the pests' ova, the individual is then faced with re-infestation when the ova hatch.

What is needed in the art is a product that is free of pesticides, but which is still capable of cleansing an individual of a lice infestation. What is needed is a pesticide-free composition and a method of use for that composition that cleanses an individual of pests and their ova. The present

invention answers this need by providing a product and a method of use for cleansing an individual of a lice infestation while being substantially free from the disadvantages of the prior commercial products.

5 Summary of the Invention

The present invention provides a composition, and a method of use thereof, for cleansing an individual of pests and their ova. By substantially aiding in the removal of undesired pests and their ova, such as lice and their nits, the composition of the present invention acts to cleanse an individual of a pest infestation. The composition of the present invention contains an acid, an alcohol, an aqueous detergent and water. In use, the pest-removing composition can be administered topically to humans, animals or any infested areas.

15 It is object of the present invention to provide a pesticide-free composition efficacious at removing pests and their ova from infested individuals.

Another object of the present invention is to provide a pest removing composition consisting essentially of an acid, an alcohol, an aqueous detergent and water.

20 A further object of the present invention is to provide a method of removing pests and their ova from infested individuals using a pesticide-free composition.

25 Still another object of the present invention is to provide a method of using a pest removing composition consisting essentially of an acid, an alcohol, an aqueous detergent and water to cleanse individuals of pest infestations.

Detailed Description of the Preferred Embodiments

30 A "pest," as used herein, is meant to include all parasites, such as arthropods, arachnids, triatomes, insects, bugs, flies, lice, fleas, mites, gnats, knits, chiggers, mosquitoes, and ticks, for example. The composition of the present invention is, therefore, intended to be used against all such pests which can be removed by the use of the present invention.

35 The present invention provides a pest removing composition consisting essentially of an acid, alcohol, an aqueous detergent and water. It should be understood that the composition of the present invention can include

other ingredients so long as those ingredients do not interfere with the pest removing ability of the composition.

The invention contains an acid in a concentration of between about 0.01 and 10 % w/w. More preferably, the invention contains between about 1 and 8 % w/w, and most preferably contains about 5 to 6 % w/w. The acid is an ionic or organic acid. Preferably, the acid is hydrochloric acid or acetic acid. More preferably, the acid is glacial acetic acid.

The composition of the present invention also includes an alcohol. Preferably, the alcohol is a short chain alcohol, such as ethanol, propanol or isopropanol. The amount of alcohol in the present invention can range from 1 to 40 % w/w. Preferably, the concentration is between about 10 and 30 % w/w, and more preferably between about 15 and 25 % w/w. Most preferably, the concentration of the alcohol is about 20 %. The alcohol is preferably isopropanol.

The composition of the present invention also includes an aqueous detergent. The concentration of the aqueous detergent within the present invention is preferably between about 7 and 21 % w/w and more preferably between about 14 and 18 % w/w. Preferably, the aqueous detergent is a surfactant, such as sodium laureth sulfate. Sodium laureth sulfate is available in commercial preparations such as Steol® CS-230, which is available from Stepan (North Field, Illinois). Steol® CS-230 is an aqueous preparation of sodium lauryl ether sulfate derived from fatty alcohols, ethoxylated to an average of two moles, and sulfated via a continuous SO₃ process. Steol® CS-230 is about 25.5 % sodium laureth sulfate. The concentration of Steol® CS-230 within the present invention is preferably between about 30 and 80 % w/w and more preferably between about 55 and 70 % w/w.

The composition of the present invention may be suitably preserved. Any suitable preservative may be used so long as it does not interfere with the pest removing ability of the composition. For example, in one embodiment of the present invention, methylparaben and propylparaben are included in the composition as preservatives.

The composition of the present invention can contain other ingredients so long as the beneficial, pest-removing nature of the invention is not adversely affected and so long as the pesticide-free nature of the invention is not altered. For example, embodiments of the present invention can contain methylparaben and propylparaben which are antimicrobial agents.

Additionally, embodiments of the present invention can contain viscosity modifiers such as sodium chloride or antipruritic agents such as camphor.

5 The composition of the present invention can be used in different forms, such as a liquid body soap or a shampoo. In other embodiments, the present invention takes the form of a gel, an emulsion, a lotion, an aerosol spray, a mousse, or a cream. Preferably, the composition of the present invention is in the form of a shampoo.

10 The present invention also includes a method of using the pest removing composition. This method includes applying the composition to the infested area, such as the hair of an individual with a lice infestation. In the case of hair, the composition is applied to the hair. The composition is left on the hair for a period of time referred to as the residence time. The residence time can vary as needed to produce effective results. The residence time can be increased in order to increase the pest removing effectiveness.
15 Alternatively, the residence time can be lowered, for example, in order to decrease any observed irritation to the patient. Preferably, the residence time is between about 1 and 30 minutes. More preferably, the residence time is between about 5 and 20 minutes, and most preferably, the residence time is approximately 10 minutes. At the end of the residence time, the composition
20 is rinsed from the area of infestation. The hair is then combed with a suitable nit comb. These treatment steps of applying, rinsing and combing can be repeated one or more times to complete the removal of the pest infestation. The time period between uses of the pest removing composition can vary as needed to remove the pest infestation from the individual. Alternatively, the
25 hair can be combed before the composition is rinsed from the area of infestation. The composition of the present invention is advantageous because it allows for frequent use, whereas the use of pesticide-containing compositions can be limited by their inherent toxicity. This ability to use the composition of the present invention increases its effectiveness in cleansing individuals of pest
30 infestations.

Any suitable nit comb can be used in the described method of use of the composition of the present invention. A suitable nit comb may be made of various materials such as metal and plastic. Metal teeth are sturdier and stiffer than those composed of materials such as plastic. Nit combs with metal
35 teeth therefore often last longer than nit combs without metal teeth. The number of teeth and the diameters of the teeth can also vary. The spacing between teeth can also vary; however, the teeth should be close enough to one

another to remove nits. The distance between teeth should be 0.3mm or less, the generally accepted width of nits attached to human hair. Preferably, a nit comb such as the ALB006 is used, which is available from Albyn Stonehaven Ltd. (Stonehaven, Scotland). This comb has 62 metal pins arranged side by side which act as the teeth of the comb. These pins extend approximately 12.5mm from a plastic piece which acts as the handle of the nit comb. The pins on either end have a diameter of 0.9mm and the 60 inner teeth have a diameter of 0.6mm. The gap between the teeth is 0.3mm.

Without being limited by these theories, it is believed that the composition of the present invention is surprisingly effective because of the synergistic effects of the composition's ingredients. It is believed that the composition of the present invention affects pests, such as lice, sufficiently such that they may be washed and removed from the infested region. Furthermore, in the cases of some pests, such as lice, it is believed that the composition of the present invention aids in the removal of the pests' ova by "loosening" or "breaking down" the substances some pests use to attach their ova to their hosts.

The effectiveness of the present invention at cleansing an individual of a pest infestation is further surprising because the composition of the present invention is neither pediculicidal nor ovicidal in standard in vitro tests used by those skilled in the art to test pest treatments.

Examples

The following specific examples will illustrate several embodiments of the present invention. It will be appreciated that other examples will be apparent to those of ordinary skill in the art and that the invention is not limited to these specific illustrative examples.

Example I

Production of a Pest Removing Composition

The following components were combined in approximate relative amounts to produce a pest removing composition.

Synthetic Camphor	0.75 % w/w
Acetic Acid	6.0 % w/w
Isopropanol	20.0 % w/w
Steol® CS-230	46.0 % w/w
Methylparaben	0.2 % w/w
Propylparaben	0.1 % w/w
Purified Water	q.s.

The alcohol was transferred into a mixing vessel. The camphor was added to this vessel and mixed until completely dissolved. The methylparaben and propylparaben were added next and mixed until fully dissolved. The acetic acid was then added and mixed until completely uniform. Next, the Steol® CS-230 was added and mixed until uniform. Finally, purified water was added to bring the composition up to its target weight.

Example II

Production of a Two Component Pest Removing Composition

Each component of the composition was produced and stored separately. The two components were mixed just prior to use. The first component was an "Alcohol/Detergent Component" and the second component was an "Acetic Acid Component." The two component composition was prepared in the following manner.

The following ingredients were combined in approximate relative amounts to make the "Alcohol/Detergent Component."

Isopropanol	22.64 % w/w
Methylparaben	0.2 % w/w
Propylparaben	0.1 % w/w
Steol® CS-230	62.83 % w/w
Purified Water	14.23 % w/w

The isopropanol and the methylparaben and propylparaben were mixed in a vessel until the parabens were completely dissolved. A portion of the Steol® CS-230 was then added and mixed until completely uniform. The purified water was then added and mixed until uniform. Steol® CS-230 was then used to dilute the mixture to its final weight and mixed until completely uniform.

The following ingredients were combined in approximate relative amounts to produce the "Acetic Acid Component."

Acetic Acid	42.86 % w/w
Methylparaben	0.2 % w/w
Propylparaben	0.1 % w/w
Purified Water	q.s.

Purified water was added to a mixing vessel. Glacial acetic acid was added to the vessel and mixed until completely uniform. The methylparaben and propylparaben were then added to the mixing vessel and mixed until completely dissolved. The resulting solution was then diluted to the final target weight with purified water.

The two components were mixed together at the point of use in relative amounts such that the "Acetic Acid Component" comprised approximately 11 2/3 % of the final combined product. The final product contained the following ingredients in the approximate relative amounts listed below.

Isopropanol	20.0 % w/w
Methylparaben	0.2 % w/w
Propylparaben	0.1 % w/w
Steol® CS-230	55.5 % w/w
Acetic Acid	5.0 % w/w
Purified Water	19.2 % w/w.

Example III

Production of a Pest Removing Composition

The following components were combined in approximate relative amounts to produce a pest removing composition.

Isopropanol	20.0 % w/w
Methylparaben	0.2 % w/w
Propylparaben	0.1 % w/w
Glacial Acetic Acid	5.0 % w/w
Purified Water	19.2 % w/w
Steol® CS-230	55.5 % w/w

The isopropanol and the methylparaben and propylparaben were mixed in a vessel until the parabens were completely dissolved. Glacial acetic acid was added to the vessel and mixed until completely uniform. A portion of the Steol® CS-230 was then added and mixed until completely uniform. The purified water was then added and mixed until uniform. Steol® CS-230 was then used to dilute the mixture to its final weight and mixed until completely uniform.

Example IV

Removal of Lice Using the Pest Removing Composition

The composition described in Example III was used in a double-blind study. Health Care professionals applied the study composition, collected lice and nits for viability assessments, used nit combs to remove nits from the hair after treatment, and performed all assessments of infestation. All qualified patients were treated with the study composition on Day 1 and could be treated on Day 15 of the study, if signs of infestation were present. The study period for an individual patient was up to approximately 29 days.

Patients were eligible to participate in the study if they signed informed consent, were at least 2 years old at screening, and had a head lice infestation confirmed by the presence of at least two live lice and at least 20 apparently viable nits. Patients were excluded from the study if they had been treated for pediculosis within four weeks before the screening evaluation, had an infestation of body or pubic lice, or had concurrent medical conditions that would interfere with efficacy and safety evaluations or

put the patient at unacceptable risk. Only one member of a household was allowed to participate, and study personnel explained adjunctive measures to remove lice and nits from the home environment to reduce the possibility of re-infestation.

5 Ten apparently viable nits were collected before treatment by cutting the hair with nits attached. Each nit was examined under a dissecting microscope, and any nits which did not appear viable were discarded and replaced. Study treatments were applied to dry hair until saturated and then
10 were allowed to remain in contact with the hair and scalp for 10 minutes before being rinsed out. Lice and nits were recovered from the rinse water by straining it through a cloth filter. Ten additional apparently viable nits were collected after treatment but before nit combing began. Subsequently, the nit comb was used for up to 20 minutes to remove any lice or nits remaining in the hair.

15 The viability of lice collected after treatment was evaluated within 1 hour after collection and after being incubated at $31.7 \pm 0.5^\circ \text{C}$ (89°F) and $50 \pm 10\%$ relative humidity for 24 ± 2 hours. The viability of nits collected before and after treatment was assessed after incubation at $31.7 \pm 0.5^\circ \text{C}$ (89°F) and $50 \pm 10\%$ relative humidity for 14 days.

20 Patients were examined on Day 15 and could be treated again if signs of infestation were present and all lice collected on Day 1 were dead after incubation for 24 hours. A patient could be discontinued as a treatment failure at Day 15 if signs of infestation were present, and one or more lice collected after treatment were alive after incubation. Clinical outcome was
25 recorded as cured, re-infestation, or treatment failure 14 days after the last application of study treatment.

30 This study was conducted in two stages. In each stage, 10 patients were treated with the study composition. The 20 patients exposed to the study composition consisted of 15 females and 5 males who ranged in age from 7 to 14 years. At screening, 9 (45%) patients had moderate infestations (11-20 live lice), and 11 (55%) patients had severe infestations (>20 live lice).

35 Viability assessments are shown in Table 1 for lice recovered and incubated after treatment and for nits collected before and after treatment on Day 1. If a second treatment was applied, lice and nits were not collected. At 1 hour after treatment, the percent of lice still alive was 44.6% in Stage 1

and 34.0% in Stage 2. After incubation, 6/231 (2.6%) lice in Stage 1, and 0/215 (0%) lice in Stage 2 were still alive.

TABLE 1

Number of Lice ¹	Stage 1 (N=10)	Stage 2 (N=10)
VISIT 1: 1 HOUR AFTER TREATMENT		
Total Number Incubated	231 (100%)	215 (100%)
Number Live	103 (44.6%)	73 (34.0%)
Number Dead	128 (55.4%)	142 (66.0%)
VISIT 1: 24 HOURS AFTER TREATMENT		
Total Number Incubated	231 (100%)	215 (100%)
Number Live	6 (2.6%)	0 (0.0%)
Number Dead	225 (97.4%)	215 (100%)
Number of Nits ²	Stage 1 (N=10)	Stage 2 (N=10)
VISIT 1: PRE-TREATMENT (DAY 1)		
Total Number Incubated	100 (100%)	100 (100%)
Number Hatched	89 (89%)	93 (93%)
Number Not Hatched	11 (11%)	7 (7%)
VISIT 1: POST-TREATMENT (DAY 1)		
Total Number Incubated	100 (100%)	100 (100%)
Number Hatched	77 (77%)	90 (90%)
Number Not Hatched	23 (23%)	10 (10%)

¹ Lice were collected from the hair and scalp, rinse water, or towel used to dry the hair after treatment. Viability was assessed 1 hour after treatment and after 24 hours of incubation.

² For each patient, 10 viable nits were collected before application of the study composition, and 10 viable nits were collected after treatment with the study composition prior to nit combing. Viability assessments were completed following incubation for 14 days.

The severity of infestation based on the number of lice or nits on the hair is summarized in Tables 2 and 3. The severity of infestation decreased at each evaluation after treatment on Day 1.

TABLE 2

Severity of Infestation	Stage 1 (N=10)	Stage 2 (N=10)
VISIT 1: DAY 1		
None (0 live lice)	0 (0%)	0 (0%)
Mild (1-10 live lice)	0 (0%)	0 (0%)
Moderate (11-20 live lice)	4 (40%)	5 (50%)
Severe (>20 live lice)	6 (60%)	5 (50%)
VISIT 2: DAY 15		
None (0 live lice)	2 (20%)	1 (10%)
Mild (1-10 live lice)	4 (40%)	7 (70%)
Moderate (11-20 live lice)	4 (40%)	2 (20%)
Severe (>20 live lice)	0 (0%)	0 (0%)
VISIT 3: DAY 29		
Number Evaluated	3 ¹	9 ²
None (0 live lice)	3 (30%)	8 (80%)
Mild (1-10 live lice)	0 (0%)	1 (10%)
Moderate (11-20 live lice)	0 (0%)	0 (0%)
Severe (>20 live lice)	0 (0%)	0 (0%)

5 ¹ Five patients were considered treatment failures at Day 15 because one or more lice collected on Day 1 were alive after incubation. These five patients did not receive a second treatment. Two patients were considered to be cured 14 days after the first treatment.

² One patient was considered to be cured 14 days after the first treatment.

TABLE 3

Severity of Infestation	Stage 1 (N=10)	Stage 2 (N=10)
VISIT 1: DAY 1		
Grade 0 (0 nits)	0 (0%)	0 (0%)
Grade 1 (1-9 nits)	0 (0%)	0 (0%)
Grade 2 (10-40 nits)	3 (30%)	5 (50%)
GRADE 3 (>40 NITS)	7 (70%)	5 (50%)
VISIT 2: DAY 15		
Grade 0 (0 nits)	2 (20%)	1 (10%)
Grade 1 (1-9 nits)	5 (50%)	6 (60%)
Grade 2 (10-40 nits)	3 (30%)	3 (30%)
GRADE 3 (>40 NITS)	0 (0%)	0 (0%)
VISIT 3: DAY 29		
Number Evaluated	3 ¹	9 ²
Grade 0 (0 nits)	3 (30%)	8 (80%)
Grade 1 (1-9 nits)	0 (0%)	1 (10%)
Grade 2 (10-40 nitx)	0 (0%)	0 (0%)
GRADE 3 (>40 NITS)	0 (0%)	0 (0%)

5 ¹ Five patients were considered treatment failures at Day 15 because one or more lice collected on Day 1 were alive after incubation. These five patients did not receive a second treatment. Two patients were considered to be cured 14 days after the first treatment.

² One patient was considered to be cured 14 days after the first treatment.

10 Clinical outcome is summarized in Table 4. Five patients in Stage 1 were considered to be treatment failures at Day 15 because one or more lice collected on Day 1 were alive after being incubated for 24 hours. These five patients did not receive a second treatment. The remaining five patients in Stage 1 and eight patients in Stage 2 were cured of their head lice infestations 14 days after the final application of the study composition. Two patients in Stage 1 and one patient in Stage 2 were cured after a single treatment.

15

TABLE 4

Clinical Outcome	Stage 1 (N=10)	Stage 2 (N=10)
Cured	5 (50%)	8 (80%)
Re-Infestation	0 (0%)	0 (0%)
Treatment Failure	5 (50%) ¹	2 (20%)

¹ A second treatment was not applied on Day 15 for these five patients.

5

It should be understood that the foregoing relates to particular embodiments of the present invention, and that numerous changes may be made therein without departing from the scope of the invention.

CLAIMS

What is claimed is:

- 5 1. A composition for removing a pest and its ova from an individual consisting essentially of an acid, an alcohol, an aqueous detergent and water.
- 10 2. The composition of Claim 1, wherein the alcohol is chosen from the group consisting of isopropanol, propanol and ethanol.
3. The composition of Claim 2, wherein the alcohol is isopropanol.
- 15 4. The composition of Claim 1, wherein the pest is a louse.
5. The composition of Claim 1, wherein the aqueous detergent is sodium laureth sulfate.
- 20 6. The composition of Claim 1, wherein the acid is chosen from the group consisting of acetic acid and hydrochloric acid.
7. The composition of Claim 6, wherein the acid is acetic acid.
- 25 8. The composition of Claim 1, wherein the individual is a human.
9. The composition of Claim 1, wherein the individual is an animal.
- 30 10. The composition of Claim 1, wherein the composition is a shampoo.

11. A method of cleansing an individual of a pest infestation comprising;

5 applying a pest removing composition to the pest infestation, wherein the pest removing composition consists essentially of an acid, an alcohol, an aqueous detergent and water;

allowing the composition to remain in contact with the infestation;

rinsing the composition from the infestation; and
combing the infestation with a nit comb.

10 12. The method of Claim 11, wherein the alcohol is chosen from the group consisting of isopropanol, propanol and ethanol.

15 13. The method of Claim 12, wherein the alcohol is isopropanol.

14. The method of Claim 11, wherein the pest infestation is a lice infestation.

20 15. The method of Claim 11, wherein the aqueous detergent is sodium laureth sulfate.

25 16. The method of Claim 11, wherein the acetic acid is glacial acetic acid.

17. The method of Claim 11, wherein the individual is a human.

30 18. The method of Claim 11, wherein the individual is an animal.

19. The method of Claim 11, wherein the composition is a shampoo.

20. A kit for treating a pest infestation comprising;
a suitable nit comb;
a composition consisting essentially of an acid, an alcohol,
an aqueous detergent and water; and
a container.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/10626

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A01N37/02 A01N59/00 //(A01N37/02, 31:02, 25:30, 25:00),
 (A01N59/00, 31:02, 25:30, 25:00)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, CHEM ABS Data, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 04128 A (EFFCON INC) 5 February 1998 (1998-02-05) page 2, line 29 - line 35 page 3, line 26 - page 4, line 17 page 6, line 13 - line 21	1-10
Y		11-20
Y	US 4 927 813 A (BERNSTEIN JOEL E) 22 May 1990 (1990-05-22) example 1 claims 1,6	11-19
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

28 August 2000

Date of mailing of the international search report

14/09/2000

Name and mailing address of the ISA
 European Patent Office, P.B. 5818 Patentstein 2

Authorized officer

INTERNATIONAL SEARCH REPORT

Int. Patent Application No.

PCT/US 00/10626

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; D.S.CARSON ET AL.: "PYRETHRINS COMBINED WITH PIPERONYL BUTOXIDE RID VS 1 PERCENT PERMETHRIN NIX IN THE TREATMENT OF HEAD LICE" retrieved from EPOQUE, accession no. PREV198886078956 XP002145941 abstract & AMERICAN JOURNAL OF DISEASES OF CHILDREN, vol. 142, 1988, pages 768-769,</p>	20
X	<p>US 4 518 593 A (JUVIN PIERRE ET AL) 21 May 1985 (1985-05-21) column 1, line 36 - line 43 column 1, line 66 - line 4</p>	1-10
P,X	<p>WO 99 18800 A (PEARLMAN DALE L ;PEARLMAN DARA B (US)) 22 April 1999 (1999-04-22) claims 1,2,7,10,11,19</p>	11-20
A	<p>EP 0 736 251 A (BENWAICHE JOSEPH) 9 October 1996 (1996-10-09) the whole document</p>	1-20
A	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; K.Y.MUMCUOGLU: "Control of human lice (Anoplura: Pediculidae) infestations: Past and present." retrieved from EPOQUE, accession no. prev199699263999 XP002145942 abstract & AMERICAN ENTOMOLOGIST, vol. 42, 1996, pages 175-178,</p>	1-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int'l Application No

PCT/US 00/10626

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9804128	A	05-02-1998	US 5902595 A AU 3901797 A CA 2261751 A EP 0932338 A	11-05-1999 20-02-1998 05-02-1998 04-08-1999
US 4927813	A	22-05-1990	NONE	
US 4518593	A	21-05-1985	NONE	
WO 9918800	A	22-04-1999	AU 1074299 A	03-05-1999
EP 0736251	A	09-10-1996	FR 2732557 A	11-10-1996